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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,001	03/11/2004	Hideshi Hattori	CU-3633	6288

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EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,001	HATTORI, HIDESHI	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 5, 2006 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 13-15 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giaever (US 3,979,184) in view of McGall et al (US 5,412,087), and in light of Arnold (US 3,982,908).

Giaever teaches a diagnostic device having a substrate 10 (i.e. substrate), transparent layer 12, second transparent layer 13 (i.e. anti-reflection layer is formed on surface of the substrate), and biological particle layer 14 (i.e. immobilization layer) in succession, wherein the second transparent layer 13 comprises globules having a diameter of 200 A to 5000 A (i.e. fine structure comprising fine particle of diameter in the range of 50 nm to 300 nm; depth of from 80 nm to 250 nm). See column 2, lines 51-68; column 3, lines 32-47; column 4, lines 20-24; and Figure 1. In addition, Giaever teaches that the nature of the second transparent layer is discontinuous (i.e. uneven structure; fine porous structure). See column 2, lines 61-63 and Figure 1. Furthermore, Giaever teaches that the biological particle layer can be antigen (i.e. probe biomolecule) and proteins for detecting antibodies. See column 4, line 56 to column 5, line 10.

Giaever does not explicitly teach that the second transparent layer is porous. However, it is well known in the coating arts that gold with a dimension of about 1 A to about 1000 A is naturally porous (see Arnold, column 2, lines 21-23 and lines 32-34). Since Giaever teaches that the second transparent layer

can comprise gold in the form of globules having 200 A to 5000 A, one of ordinary skill in the art at the time of the invention would recognize that gold globules of 200A to 1000A, as taught by Giaever, would necessarily be porous.

However, Giaever fails to teach that the immobilization layer is formed in a pattern.

McGall et al teach probes immobilized in an array format, in order to provide discrete locations for distinctive probes, which can then be used to perform a simultaneous, parallel assay to detect different targets. See column 11, lines 13-35. In addition, McGall et al teach that the probes can be proteins and the targets can be antibodies. See column 4, lines 22 and 52-53.

It would have been obvious to one of ordinary skill in the art at the time of the invention to place the probes of Giaever in an array format, as taught by McGall et al, in order to provide discrete locations for distinctive probes, which can then be used to perform a simultaneous, parallel assay to detect different targets. The benefit of being able to simultaneously detect a plurality of distinct targets through spatial differentiation of distinct probes provides the motivation to combine Giaever and McGall et al references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in replacing the probes of Giaever with the probe array of McGall et al, since Giaever teaches protein probes, and the probe array McGall et al can include proteins, thereby allowing the pattern of McGall et al to be deposited upon the globules of Giaever.

5. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giaever (US 3,979,184) in view of McGall et al (US 5,412,087) as applied to claims 13-15 above, and further in view of Noblett (US 6,362,004 B1).

Giaever and McGall et al references have been disclosed above, but fail to teach a mark formed on the substrate for positional detection.

Noblett reference teaches fiducial marks located on predetermined locations with respect to a microarray sample, in order to position and align the sample with greater precision for detection purposes. See abstract and column 3, lines 24-35.

It would have been obvious to one of ordinary skill in the art to modify the apparatus of Giaever and McGall et al with fiducial marks located on predetermined locations with respect to the probe array, as taught by Noblett, in order to position and align a sample with greater precision for detection purposes. The advantage of more accurate detection, as taught by Noblett, provides the motivation to combine Noblett reference with Giaever and McGall et al references. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including the fiducial marks, as taught by Noblett, in the apparatus of Giaever and McGall et al, since Giaever and McGall et al teach that only a certain part of the substrate comprises immobilized antigen (see Giaever, column 4, lines 57-60), and the fiducial marks of Noblett provides a means to correctly locate the immobilized antigen.

Response to Arguments

6. In the Remarks section, pages 4-6 of the response filed July 5, 2006, Applicant traverses the prior art rejections of the previous Office Action. Specifically, Applicant contends three issues:

(1) Applicant argues that the previous Office Action was improperly made Final since the cited references have not been cited in any previous IDS, nor have the claims been amended to require newly cited art. See page 5, 2nd paragraph.

(2) Applicant contends that Giaever neither teaches nor discloses an immobilization layer, much less the claimed patterned immobilization layer. See page 5, 3rd paragraph. Applicant also argues in the same paragraph that the purpose of the immobilization layer is to increase analysis accuracy, and not "enabling the performing of many different assays simultaneously".

(3) Applicant argues that McGall does not reach or suggest a discrete immobilization layer, much less the claimed patterned immobilization layer. Specifically, Applicant contends that McGall teaches away from the claimed invention since there is "no suggestion in McGall of an immobilization layer permitting a surface free energy gradient". See page 6, 1st paragraph.

Applicant's arguments have been fully considered, but are not persuasive to overcome the applied prior art rejections.

In regards to Applicant's first argument (1) above, the considered claims in the previous Office Action had in fact been amended to include ***new*** claims 10-21, with the cancellation of all original claims 1-9. See claim amendments filed November 17, 2005. Because the pending claims are new, and also because the claims included subject matter not previously claimed (i.e. particle diameter in a range of 50 nm to 300 nm [claim 10]; depth of from 80 nm to 250 nm [claim 11]), an additional search was deemed necessary for a prior art search. Since art was found to teach the claimed invention, the rejection was made Final in proper accordance with the rules for a second action. See MPEP 706.07(a).

In regards to Applicant's second argument (2) above, Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Specifically, Applicant merely alleges that Giaever fails to teach the claimed immobilization layer, and that Applicant's immobilization layer permits a "different surface free energy from the substrate surface". See page 5, 3rd paragraph. However, "different surface free energy" is not a limitation required by the claims. The claims merely recite as embodiments a substrate, anti-reflection layer, and immobilization layer formed in a pattern. In fact, there is absolutely no mention whatsoever of "different surface free energy" in the claims, and any traversal on these grounds therefore fails to overcome the applied prior

art. In addition, Applicant states that the claimed immobilization layer is formed so that analysis accuracy can be increased, "rather than enabling the performing of many different assays simultaneously". See page 5, 3rd paragraph. Although Applicant may have a separate reason for providing a patterned immobilization layer than what is used as motivation to combine Giaever and McGall et al references (i.e. ability to perform simultaneous assays), a difference in reason for providing patterned immobilization does not preclude a proper obviousness rejection under Giaever and McGall et al. There may be numerous reasons for providing an immobilization layer on a substrate, and although those reasons may not be the same as that advocated by Applicant, it does not follow that Applicant's invention is patentably distinct from other devices that include a patterned immobilization layer because those devices would have ***the same embodiments*** as that of Applicant's device. Since the instant claims only recite " an immobilization layer formed in a pattern for immobilizing a probe biomolecule thereon" without further limits on surface free energy or other embodiments, prior art that teaches any patterned probe would read on the recitation. Because the combination of Giaever and McGall et al produces an apparatus that includes an immobilization layer placed in an array format, the combination is properly applied as an obviousness rejection against the instant claims.

In regards to Applicant's third argument (3) above, Applicants seem to be stating the same argument as presented in Applicant's second argument (2) above. The second argument has been thoroughly considered and a rebuttal presented supra. Since the third argument is essentially the same as the

second, and it has been shown that the combination of Giaever and McGall et al references is proper in teaching the instant claims, further statements are not necessary.

In light of the statements above, Applicant's arguments are not found convincing and the instant claims remained rejected.

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1641

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